

CLAIMS

What is claimed is:

1. A stable non-aqueous composition of an active agent comprising:
 - a) an active agent containing powder wherein the active agent hydration in said powder is less than about 10%; and
 - b) at least one anhydrous, aprotic, hydrophobic, non-polar, low-reactivity vehicle, wherein said active agent is selected from the group consisting of proteins, proteinaceous compounds, and nucleic acids.
2. The composition of Claim 1 wherein at least about 80% of the active agent remains stable for at least one month at 37°C.
3. The composition of Claim 1 wherein said active agent hydration is less than about 5%.
4. The composition of Claim 1 wherein said vehicle is selected from the group consisting of perhalohydrocarbons, unsubstituted saturated hydrocarbons, halogenated hydrocarbons, esters of unsubstituted saturated or halogenated hydrocarbons and ethers of unsubstituted saturated or halogenated hydrocarbons.
5. The composition of Claim 1 wherein said vehicle is selected from the group consisting of MO, PFD, MF, PTA and TD.
6. The composition of Claim 1 wherein said powder comprises up to about 30% (w/w) of said composition.

7. The composition of Claim 1 wherein said active agent is a protein selected from the group consisting of Factor IX, Factor VIII, alpha-interferon, consensus interferon, beta-galactosidase, lactate dehydrogenase, chymotrypsin, trypsinogen, an antibody, and analogs thereof.

8. The composition of Claim 1 wherein said active agent is a nucleic acid selected from the group consisting of DNA, RNA and oligonucleotides.

9. The composition of Claim 8 wherein said nucleic acid is in the form of at least one selected from the group consisting of a nucleic acid/lipid complex, a nucleic acid-containing liposome, a ribozyme, a viral vector, a virosome, nucleic acid-containing dendrimers, nucleic acid-containing cationic polymers and nucleic-acid-containing PLGA particles.

10. The composition of Claim 1 wherein said active agent is pharmaceutically useful.

11. A method for preparing the composition of Claim 1 comprising suspending an active agent-containing powder with active agent hydration less than about 10% in at least one anhydrous, aprotic, hydrophobic, non-polar, low-reactivity vehicle.

12. A method for treating a subject suffering from or susceptible to a condition which may be alleviated or prevented by administration of an active agent according to Claim 1, said method comprising administering to said subject an effective amount of the composition of Claim 1.

13. The method of Claim 12 wherein said condition is hemophilia and the active agent in said composition is selected from the group consisting of Factor VIII, Factor IX, and analogs thereof.

14. The invention of any of Claims 1 and 11 wherein said powder comprises about 10 to about 30% (w/w) of said composition.

15. The invention of any of Claims 1 and 12 wherein administration of the composition is via a route selected from the group consisting of parenteral, transdermal, mucosal, oral and enteral.

16. The invention of any of Claims 1 and 12 wherein administration of the composition is via an implantable delivery device.

17. The invention of any of Claims 1 and 12 wherein administration of the composition is long-term continuous administration.